K022240
Page 1 of 2

AUG 0 6 2002

GE Medical Systems

ELGEMS Ltd.
10 Hayozma St., P.O. Box 170
Tirat Hacarmel, 30200, Israel

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87(h)

Submitter: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Contact Person: Hemy Neuman
Quality, Safety and Regulatory Manager
Telephone: +972-4-856-3667; Fax: +972-4-857-7664

Date Prepared: June 16, 2002

Device Name: Millennium Mobile MG Imaging System.
Emission Computed Tomography System, 21 CFR 892.1200, 90-KPS

Marketed Device: GE Medical System's Millennium MG System; 510(k) Number K962738, and eNTEGRA Processing and Review Workstation; 510(k) Number K000395, both currently in commercial distribution.

Device Description:

The GE Millennium Mobile MG System is composed of a gantry, patient table, image acquisition hardware and software, an operator console, a processing and review workstation, and associated accessories. Materials and construction are equivalent to the Millennium MG System and eNTEGRA Workstation and are compliant with CISPR 11, IEC 801, UL2601-1, IEC 60601-1 and associated collateral standards, and applicable sections of 21 CFR Subchapter J.

Indications for Use:

The Mobile Millennium MG Imaging System is intended for use as a diagnostic imaging system which, when used with appropriate radiopharmaceuticals, produces images representative of the internal distribution of radioactivity in the head or body. It is designed to acquire, display, process, archive, and communicate data for whole body, planar, tomographic (SPECT), multi-slice, and attenuation corrected images. The system allows for the acquisition of data for high resolution three dimensional, static, gated, or dynamic images of biochemical and metabolic processes. It can be operated in a mobile as well as a fixed site environment.

Comparison with Predicate Device:

The GE Millennium Mobile MG System is a modification of, and is comparable and substantially equivalent to the currently marketed GE Millennium MG System and the GE eNTEGRA Processing and Review Workstation. This system has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended use as the predicate devices.

Summary of Studies:

The device has been evaluated for electrical, mechanical, and radiation safety, and conforms to applicable medical device safety and performance standards.

K022240
Page 2 of 2

Conclusion:

Intended use and fundamental scientific technology are the same as the legally marketed GE Millennium MG System and eNTEGRA Workstation. The design and development process of the manufacturer conforms to 21 CFR 820, and ISO 9001/ EN 46001 quality systems. The device conforms to applicable medical device safety and performance standards. Results of the testing and standards conformance described above demonstrate, in the opinion of GE Medical Systems, that the Millennium Mobile MG System is substantially equivalent to the currently cleared Millennium MG System and the eNTEGRA Workstation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems W-709
P.O. Box 414
MILWAUKEE WI 53201

Re: K022240
Trade/Device Name: Millennium Mobile MG System and eNTEGRA Workstation
Regulation Number: 21 CFR 892.1200
Regulation Name: Emmission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: June 16, 2002
Received: July 11, 2002

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K022240

Device Name: **Millennium Mobile MG System and eNTEGRA Workstation**

Indications for Use

The Mobile Millennium MG Imaging System is intended for use as a diagnostic imaging system which, when used with appropriate radiopharmaceuticals, produces images representative of the internal distribution of radioactivity in the head or body. It is designed to acquire, display, process, archive, and communicate data for whole body, planar, tomographic (SPECT), multi-slice, and attenuation corrected images. The system allows for the acquisition of data for high resolution three dimensional, static, gated, or dynamic images of biochemical and metabolic processes. It can be operated in a mobile as well as a fixed site environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022240